REMARKS

Drawings

Applicant acknowledges that the application was filed with informal drawings that are acceptable for examination purposes. Applicant will submit formal drawings upon allowance of the application.

Priority

Applicant has amended the Specification to update the status of Application Serial 09/356,142 by inserting "now United States Patent No. 6,217,914" after "July 19, 1999," in paragraph no. [0001], in compliance with the request made of Applicant in the Office Action.

Specification

Applicant has amended the specification at page 9, line 24, to correct the heading to read BRIEF DESCRIPTION OF THE DRAWINGS, to cure the informality objected to in the Office Action.

Applicant has amended claim 19 at line 3 to delete the "a" before "(a)" to correct the informality objected to in the Office Action.

Claim Rejections – 35 U.S.C. § 112

Claims 1-20 were rejected under 35 U.S.C. § 112, first paragraph, because the specification was deemed not to enable a person skilled in the art to make and/or use the invention commensurate in scope with the claims.

Claims 1-20 were rejected under 35 U.S.C. § 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between steps. Specifically, the claims do not set forth the steps for stabilizing the ascorbic acid.

Applicant addresses the issues of enablement and step omission, below, together with the Applicant's remarks concerning the 35 U.S.C. §103(a) claim rejections.

Claims 1-17 and 20 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

Claims 1 and 17 recite "10%" which was deemed indefinite because it was uncertain what is the basis for the percentage. Claims 2-26, which depend from claim 1 were therefore also rejected. Applicant has amended claims 1 and 17 to provide the required basis for the percentage, namely, weight to volume (w/v).

Claims 9 and 20 recite "microspheres and other encapsulants" which was deemed indefinite. The Office Action suggested claiming "encapsulants" separately in the list of each respective claim. Applicant has amended claims 9 and 20 to adopt the suggestion of the Office Action.

Claims 9 and 20 recite the transitional phrase "comprises" which was deemed to render the claims indefinite. The Office Action suggested "wherein the composition is in the form of" or "wherein the composition is formulated as." Applicant has amended claims 9 and 20 to adopt the suggestion of the Office Action, namely, "wherein the composition is in the form of."

Claims 9, 11, 16 and 20 were rejected as indefinite for claiming a broad range or limitation with a narrow range or limitation that falls within the broad range or limitation in the same claim. Applicant has amended claims 9, 11, 16 and 20 to recite the narrow limitations or ranges separately in the list of elements in each respective claim.

Claim 11 was rejected as indefinite for reciting "(o) any combination of (a)-(o)" where the recitation of "o" was redundant. Applicant has amended the claim to remove the redundancy.

Claim Rejections 35 –U.S.C. § 103

Claims 1-20 were rejected under 35 U.S.C. § 103(a) as obvious over Schinitsky, et al. (U.S. Patent No. 4,938,969), in view of Murad (U.S. Patent No. 5,804,594), and Herstein (U.S. Patent No. 5,902,591). The Office Action acknowledges that the cited art does not expressly disclose the use of pretreated ascorbic acid.

Double Patenting

Claims 1-20 were rejected under the judicial Doctrine of Obviousness-Type Double Patenting in light of U.S. Patent No. 6,217,914 and provisionally over claims 32-51 of U.S. Patent Application No. 09/732,385.

During prosecution of related U.S. Patent Application No. 09/732,385, the Examiner and the Applicant agreed that the term "pretreated" was defined in Applicant's specification. It was further agreed to adopt the definition as set forth in Applicant's specification. Applicant respectfully submits that the same is true in the instant case and requests adoption of the definition of the term "pretreated" as found in Applicant's specification in paragraph [00028] on page 12, namely:

> It has been found that ascorbic acid-based topical formulations in which a substantial portion of the ascorbic acid has been "pretreated" exhibit particularly good storage stability. As noted above, for the purposes of this application, pretreated ascorbic acid refers to ascorbic acid that has been dissolved in water at a relatively high temperature to form a concentrated ascorbic acid solution. Typically, the ascorbic acid is dissolved in water at between about 60 to about 90^0C (e.g., between about 75 to about 80^0C) to form a concentrated solution which contains at least about 20% (w/v) ascorbic acid. During this pretreatment, the ascorbic acid is dissolved in the acid form, i.e., the resulting solution will have a relatively low pH (circa 2.0-2.5). After dissolution, the

> concentrate is generally heated for an additional period of time (e.g., 0.25 to 1.0 hour) and cooled to below about 400C before being incorporated into the final formulation. If the pretreated concentrate is to be stored prior to formulation, it is preferably stored at room temperature or below (e.g., about 3 to about 20^0C) and/or under conditions which exclude oxygen-containing gases such as air (e.g., in a sealed container or blanketed with an inert gas such as argon or nitrogen). In the present compositions, commonly at least about 10% of the ascorbic acid present has been pretreated. Typically, no more than about 50% of the ascorbic acid present has been pretreated. This allows the enhanced stability properties to be obtained while minimizing the additional processing steps and cost associated with the pretreatment of the ascorbic acid.

The definition above is materially identical to the definition accepted in the parent case. Applicant respectfully believes that use of the defined term "pretreated" in the claims brings claims 1-20 into compliance with 35 U.S.C. § 112, first and second paragraphs, and also overcomes the claim rejections based on 35 U.S.C § 103.

Claims 1-20 were rejected under the judicial Doctrine of Obviousness-Type Double Patenting in light of U.S. Patent No. 6,217,914 and provisionally over claims 32-51 of U.S. Patent Application No. 09/732,385. The official Action provides that a timely filed Terminal Disclaimer pursuant to 37 C.F.R. § 1.321(c) may used to overcome an actual or provisional rejection based on non-statutory double patenting. Accordingly, Applicant submits herewith a terminal disclaimer in compliance with 37 C.F.R. § 1.321(c).

Applicant respectfully believes that claims 1-20 are allowable. Applicant respectfully requests reconsideration by the Examiner, withdrawal of claim rejections, and advancement of the claims to allowance.

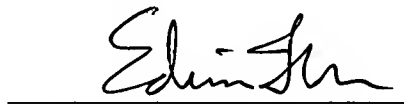
CONCLUSION

The present paper constitutes a complete response to the official Action mailed December 18, 2001. Applicant respectfully requests that the remarks herein be considered to a favorable conclusion of the case. Applicant believes that the case is in condition for allowance and earnestly requests a Notice of Allowance at the earliest possible time. No fees are believed due with this response. Should the Examiner have any questions, comments or

suggestions that would expedite the prosecution of the present case to allowance, Applicant's undersigned representative earnestly requests a telephone conference.

Respectfully submitted,

GARDERE WYNNE SEWELL LLP



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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Lorraine Faxon Meisner

Serial No.: 09/997,663

Filed: November 29, 2001

For: METHOD FOR TREATMENT OF AGING OR DAMAGED SKIN

Examiner: Frank Choi

Art Group: 1616

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN ACCORDANCE WITH RULE 1.121

Please replace paragraph number [0001] with the following rewritten paragraph:

[0001] This Application is a continuation-in-part of, and claims priority from co-pending U.S. Patent Application Serial No. 09/732,385, filed December 7, 2000, which is a continuation of Application Serial No. 09/356,142, filed July 19, 1999, now United States Patent No. 6,217,914, which claims priority from [benefit of] Provisional Application Serial No. 60/125,356, filed March 19, 1999.

Please replace the heading at page 9, line 24, with the following replacement heading:

BRIEF DESCRIPTION OF THE DRAWINGS [FIGURES]

In the Claims

Please amend the claims to read as follows:

1. (AMENDED) A composition comprising:

at least about 10% (w/v) [of the] ascorbic acid, wherein the ascorbic acid comprises pretreated ascorbic acid;

an amino sugar; and

water.

9. (AMENDED) The composition of claim 1, wherein the composition [comprises] is in the form of a serum, a lotion, an ointment, a cream, a gel, a foam, an emollient, microspheres, [and other] encapsulants, [including] time-release encapsulants, a patch, a transdermal patch, a shampoo, a skin or hair conditioner, a pomade, a spray or aerosol, a water-based solution, an oil/water emulsification, an unguent, a salve, a soap, a wax, a paraffin, a gum, a tonic, an elixir, an embrocation, a lenitive, a liniment, a medicament, a balm, a balsam, a palliative, or any combination of administration forms suitable for topical application on the skin.

11. (AMENDED) The composition of claim 1, wherein the composition further comprises one or more ingredients selected from the group consisting of (a) one or more non-toxic zinc salts, (b) one or more tyrosine compounds, (c) one or more antibacterial agents, (d) one more dyes, (e) one or more fragrances, (f) one or more surfactants, (g) one or more thickeners, (h) one or more antioxidants, (i) one or more pharmaceutically acceptable carriers, (j) one more tissue compatible vehicles, (k) one or more humectants, (l) one or more moisturizers, (m) [(k)]one or more polymers, [(l) one or more polymers] (n) [(m)]one or more cross-linking agents, (o) [(n)] one or more waxes [or], (p) one more resins, and [(o)] (q) any combination of (a) – [(o)](p).

16. (AMENDED) The composition of claim 1, wherein the composition further comprises one or more ingredients selected from the group consisting of: almond meal, alumina, aluminum oxide, aluminum silicate, apricot seed powder, attapulgite, barley flour, bismuth oxychloride, boron nitride, calcium carbonate, calcium phosphate, calcium pyrophosphate, calcium sulfate, cellulose, chalk, chitin, clay, corn cob meal, corn cob powder, corn flour, corn meal, corn starch, diatomaceous earth, dicalcium phosphate,

dicalcium phosphate dihydrate, fullers earth, hydrated silica, hydroxyapatite, iron oxide, jojoba seed powder, kaolin, magnesium trisilicate, mica, microcrystalline cellulose, montmorillonite, oat bran, oat flour, oatmeal, peach pit powder, pecan shell powder, polybutylene, polyethylene, polyisobutylene, polymethylstyrene, polypropylene, polystyrene, polyurethane, nylon, teflon [(i.e. polytetrafluoroethylene)], polytetrafluoroethylene, polyhalogenated olefins, pumice rice bran, rye flour, cericite, silica, silk, sodium bicarbonate, sodium silicoaluminate, soy flour synthetic hectorite, talc, tin oxide, titanium disoide, tricalcium phosphate, walnut shell powder, wheat bran, wheat flour, wheat starch, zirconium silicate, or mixtures thereof.

17. (AMENDED) A composition for treating an inflammatory skin ailment, the composition comprising:

at least about 5.0% (w/v) ascorbic acid, wherein at least about 10% (w/v) of the ascorbic acid is pretreated ascorbic acid;

at least about 10% (w/v) of glucosamine;

a non-toxic zinc salt;

a tyrosine compound; and

water, wherein the composition has a pH of more than 3.5.

19. (AMENDED) The method of claims 13, wherein the composition further comprises one or more ingredients selected from the group consisting of [a] (a) one or more non-toxic zinc salts, (b) one or more tyrosine compounds, (c) one or more antibacterial agents, (d) one or more dyes, (e) one or more fragrances, (f) one or more surfactants, (g) one or more thickeners, (h) one or more antioxidants and (i) any combination of (a)-(h).

20. (AMENDED) The composition of claim 13, wherein the composition [comprises] is in the form of a serum, a lotion, an ointment, a cream, a gel, a foam, an emollient, microspheres, [and other] encapsulants, [including] time-release encapsulants, a patch, a transdermal patch, a shampoo, a skin or hair conditioner, a pomade, a spray or aerosol, a water-based solution, an oil/water emulsification, an unguent, a salve, a soap, a wax, a paraffin, a gum, a tonic, an elixir, an embrocation, a lenitive, a liniment, a medicament, a balm, a balsam, a palliative, or any combination of administration forms suitable for topical application on the skin.